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| 10/787,098      | 02/27/2004  | Shaun Jordan         | Q-69854             | 8004             |

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EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/787,098

**Applicant(s)**

JORDAN ET AL.

**Examiner**

Deborah Crouch, Ph.D.

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

AD

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Applicant's arguments filed March 10, 2005 have been fully considered but they are not persuasive. The amendment has been entered. Claim 1 is pending.

This application has been transferred to Deborah Crouch, Ph.D., and AU 1632.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 remains rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for reasons set forth in the office action mailed November 12, 2004.

Claim 1 is drawn to a congenic rat comprising a mutant GPR10 gene, wherein said congenic rat is obtained by crossing a Otsuka Long-Evans Tokushima Fatty (OTELF) rat (ATCC No. 72016) with a wild-type rat, and wherein said congenic rat exhibits a prolonged immobilization time in a forced swim test compared to said wild-type rat and a prolonged time spent in open arms in an elevated plus-maze test compared to said wild-type rat, and wherein said mutant GPR10 gene contains a G to A substitution at the third position of the coding region.

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons set forth in the office action mailed November 12, 2004. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Applicant argues that the claimed rat can be used as a model for the treatment of depression. Applicant argues that that, with regard to the known function of the GPR10 gene, a gene can have many functions. Applicant argues that Bhattacharyya teaches that GPR10 may have roles in processes other than blood pressure regulation. Applicant argues that Bhattacharyya completed their initial studies in rats, indicating an acceptance that rats were representative of humans. Applicant argues that Bhattacharyya only looked for a correlation between GPR10 and blood pressure. Applicant argues that WO 03/080099 teaches human GPR10 to be associated with diseases of the central nervous system in view of the tissue expression profile including "manic excitement" and "depression." Applicant argues that other researchers value the rat as a model of the human condition. These arguments are not persuasive.

The examiner acknowledges the use of rats as experimental models in the study of human disease and condition. However, the use of rats as such models is not the reasoning behind the rejection. The examiner stated that the mutations in GPR10 do not manifest the same phenotype in humans, mice and rats (office action mailed November 12, 2004). Thus, if the phenotypes are variable, the rat cannot be said to mimic a human condition when the phenotype obtained, a depression-like condition, is not recognized by the art as being associated with depression. Thus, the rat lacks a specific utility. Also, the previous examiner stated that using the rats as an assay to determine GPR10 function lacks a substantial utility. Further experimentation would be required to determine a use for the rats. WO 03/080099, page 55, states that GPR10 is highly expressed in areas of the nervous system in the Alzheimer's disease state (page 55, lines 4-5). The aberrant expression in a diseased state does not reflect a function for a protein in the healthy animal. The discussion in '099 of depression and manic excitement relate only to the class of G-protein coupled receptors and not GPR10 (page 72, lines 26- on). This disclosure does provide either depression or manic

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excitement as being associated with GPR10. Rather the list of symptoms indicate that G-protein coupled receptors are involved in many physiological systems (page 72, line 11 to page 72, line 2).

Claim 1 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons set forth in the office action mailed November 12, 2004. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that the rat claimed can be used to screen compounds useful for treating psychiatric diseases, such as depression. Applicant argues that they are claiming a rat having a particular mutation. This argument is not persuasive.

As stated above, and in the office action mailed November 12, 2004, there is no evidence of record or in the art that the claimed rats are useful as models of depression because GPR10 has no known association with this condition. Thus, the rats have no enabled use as assay models for depression therapy.

The claims remain free of the prior art. At the time of filing the prior art did not teach or suggest a congenic rat comprising a mutant GPR10 gene, wherein said congenic rat is obtained by crossing a Otsuka Long-Evans Tokushima Fatty (OTELF) rat (ATCC No. 72016) with a wild-type rat, and wherein said congenic rat exhibits a prolonged immobilization time in a forced swim test compared to said wild-type rat and a prolonged time spent in open arms in an elevated plus-maze test compared to said wild-type rat, and wherein said mutant GPR10 gene contains a G to A substitution at the third position of the coding region.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

April 28, 2005